K132996
Page 1 of 2

IsoRay MEDICAL

DEC 17 2013

3.0 510(k) Summary Required by 21 CFR § 807.92(c):

3.1. **Submitter**: IsoRay Medical, Inc.

3.2. **Address**: 350 Hills Street, Suite 106
Richland, WA 99354-5411

3.3. **Telephone and Fax Numbers**: 509-375-1202
(Fax) 509-375-3473

3.4. **Contact Person**: Fredric Swindler - fswindler@isoray.com

3.5. **Date of preparation of this Summary**: 09/06/2013

3.6. **Device Name, Regulatory and Classification Information**:

3.6.1. **Trade Name**: GliaSite® RTS
Cesitrex

3.6.2. **Common Name**: Radionuclide source and radionuclide applicator

3.6.3. **Classification Name**: Radionuclide Brachytherapy Source, (Per 21 CFR §892.5730), and Radionuclide Manual Applicator System, (Per 21 CFR §892.5650).

3.7. **Marketed device to which equivalence is claimed**: The modified GliaSite RTS that is the subject of this submission is substantially equivalent to the GliaSite RTS as described in 510(k) #K111931 (SE 08/05/11).

3.8. **Product Description**: The GliaSite® RTS is a radiation therapy system that includes the GliaSite Catheter Tray, GliaSite Access Tray, and Iotrex®, (^{125}I-HBS) or Cesitrex, (liquid ^{131}CsCl) Radiotherapy Solutions. The GliaSite Catheter Tray includes the GliaSite catheter and accessories to assist with the implantation of the catheter. The GliaSite catheter is a double balloon applicator that positions the radiation source within the resected cavity for radiation delivery. The GliaSite RTS Catheters are provided in three balloon sizes: 2 cm, 3 cm, and 4 cm. The GliaSite RTS Access Tray contains the items needed for the afterloading and retrieval of the Iotrex or Cesitrex. Iotrex and Cesitrex radiotherapy solutions are the radiation sources that can be used with the GliaSite RTS.

3.9. **Statement of intended use compared to the currently marketed predicate device**: The intended use of modified device is as follows:

> The GliaSite RTS with Cesitrex is intended to deliver intracavity radiation therapy (brachytherapy) in patients with malignant brain tumors following resection surgery.

This is identical to the legally marketed predicate device, Iotrex, Reference No. 8150, (^{125}I)HBS, which is a component of the GliaSite RTS as described in 510(k) No. K111931 (SE 08/05/2011).

IsoRay MEDICAL

3.10. **Patient Population**: Patients requiring radiation therapy for malignant diseases of the brain.

3.11. **Statement of Technological Characteristics**: The intended use and technological characteristics of the proposed radiation source, (Cesitrex), for GliaSite RTS are identical to the GliaSite RTS with Iotrex predicate as described in 510(k) No. K111931. Both the proposed Cesitrex and the predicate, Iotrex, are radionuclides which have similar energies and are used for low dose brachytherapy. Both Cesitrex and Iotrex have been shown to be able to deliver the same radiation dose to the Planned treatment Volume.

3.12. **Assessment of Non-Clinical Performance** Data: Based on the results of bench testing, both Cesitrex and Iotrex comply with identical acceptance criteria including simulated clinical use testing, balloon and catheter leak testing, infusion port to catheter shaft tensile strength testing, characterization of the radionuclide source, and diffusion testing of amount of radioactive material that diffused from the GliaSite RTS Catheter's balloons.

3.13. **Conclusion Drawn from Testing**: Based on the results of the analysis and testing performed on the proposed device it has been demonstrated that Cesitrex when used as the radiation source for the GliaSite RTS is safe and effective and exhibits equivalent performance to the predicate device, GliaSite RTS with Iotrex.

3.14. **Safety and Effectiveness**: To ensure that the devices are safe and effective, all finished products are tested and must meet all required release specifications before distribution. The testing required for release includes, but is not limited to leak testing, testing for external contamination, apparent activity, sterility, pyrogens, and labeling. The required testing is defined by written and approved procedures that conform to the product design specifications. The testing for the GliaSite RTS is detailed in the Device Master Record.

350 Hills St., Suite 106 - Richland, WA 99354-5411
Phone: 509.375.1202 Toll Free: 877.447.6729 Fax 509.375.3473 info@isoray.com

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 17, 2013

IsoRay Medical, Inc.
% Mr. Fredric Swindler
Vice President, Regulatory Affairs and Quality Assurance
350 Hills Street, Suite 106
RICHLAND WA 99354

Re: K132996
Trade/Device Name: Cesitrex to be used with GliaSite® Radiation Therapy System (RTS)
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: September 6, 2013
Received: September 24, 2013

Dear Mr. Swindler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Section 2.0

Indications for Use

510(k) Number: K132996

Device Name: GliaSite Radiation Therapy System (RTS)

Indications for Use:

The GliaSite RTS with Cesitrex, (Liquid ^{131}CsCl), is intended to deliver intracavity radiation therapy (brachytherapy) in patients with malignant brain tumors following tumor resection surgery.

Prescription Use __X__ (Per 21 CFR § 801.109) OR Over-The-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael D. O'Hara

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) _____K132996_____